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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,052	04/22/2002	Roger New	1417-212	5183

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EXAMINER	
SHIBUYA, MARK LANCE	

ART UNIT	PAPER NUMBER
1639	

DATE MAILED: 12/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/019,052	NEW ET AL.	
	Examiner	Art Unit	
	Mark L. Shibuya	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 September 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) *13-31* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2/22/05 & 12/27/01*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *See Continuation Sheet*.

DETAILED ACTION

1. Claims 1-31 are pending. Claims 13-31 are withdrawn from further consideration as drawn to a non-elected Invention. Claims 1-12 are examined.

Election/Restrictions

2. Applicant's election with traverse of Group I, claims 1-12 in the reply filed on 9/1/2005 is acknowledged. The traversal is on the ground(s) that that the reference of Toth et al., US 5,882,645 does not teach why disclosed head groups are expected to form an epitope. This is not found persuasive because the reference of Toth et al., at col. 3, disclose a compound comprising a lipophilic anchor, reading on the claimed tail groups, and at least 2 amino acid moieties for joining molecules, such as drugs, that read on the claimed head groups; and wherein such conjugates elicit the production of rabbit antibodies specific for the head groups. These elicited rabbit antibodies would bind more than one of the head groups. Toth et al., e.g., at col. 1, teach peptides that can induce antibodies and can be rendered more immunogenic by conjugation to a carrier molecule. Furthermore, other prior art teaches the claimed invention, (see below prior art rejections). Therefore, the examiner respectfully submits that there is no special technical feature linking the different Groups of Invention.

The requirement is still deemed proper and is therefore made FINAL.

3. Claims 13-31 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 9/1/2005.

> The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.
>
> In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**
>
> Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Priority

4. This application is the national stage of International Application PCT/GB00/02465, filed 6/27/2000.

5. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in the United Kingdom on 06/28/1999. It is noted, however, that applicant has not filed a certified copy of the United Kingdom 9915074.0 application.

Information Disclosure Statement

6. The information disclosure statement filed 27 Dec. 2001 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. It has been placed in the application file, but the information referred to therein in regard to foreign language publication cited as No. 3, to Weismuller et al., has not been considered.

7. The information disclosure statement filed 2/22/2005 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because no publication dates have been provided for the cited documents. It has been placed in the application file, and the information referred to therein has been considered as to the merits; however the citation has been lined through on the form IDS (PTO-1449).

Nucleotide and/or Amino Acid Sequence Disclosure

8. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1)

and (a)(2). A computer readable form (CRF) of the sequence listing was submitted. However, the CRF could not be processed by the Scientific and Technical Information Center (STIC) for the reason(s) set forth on the attached Raw Sequence Listing Error Report.

Applicant must provide:

a. An substitute computer readable form (CRF) copy of the "Sequence Listing".

b. A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

Applicant is required to comply with the corrections for the sequence listing as per above as part of a complete response to this official action. Please see **attached Notice to Comply** and **Raw Sequence Listing Error Report**.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 1-12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to

one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is for lack of written description.

Vas-Cath Inc. v. Mahurkar, 19 USPQ 2d 1111, 1117, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 116).

The skilled artisan cannot envision the detailed chemical structure of the encompassed genus of head groups that will interact with the any single ligand, and could not envision that applicant possessed the claimed compositions for use as drugs, prophylactics and diagnostics, as contemplated in the specification and claimed (in claim 12); and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. The specification does not describe the treatment of any disease with the compound; does not describe actual binding to any particular ligand, but only the increase in tumor necrosis factor (TNF) secretion from cultured macrophages, and increased activity (TNF?) in the blood of mice fed with individual conjugates comprising amino acid or peptide head groups. The specification does not describe any particular molecules, other than amino acids and peptides, that elicit a biological response, and so by extension, may be binding to ligands. The identity of these ligands is not described. Applicant has not described a sufficient number of species of head groups that bind to

the vast genus of ligands, including various cell surface receptors, small molecule drugs, nucleic acid sequences, etc., so that one of skill in the art would not envision that applicant possessed the full scope of the claimed invention. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ2d 1601 at 1606 (CAFC 1993) and Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016.

One cannot describe what one has not conceived. See Fiddes v. Baird, 30 USPQ2d 1481, at 1483. In Fiddes, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 U.S.C. § 112 is severable from its enablement provision (see page 1115).

Claim Rejections - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 in line 3 states: "wherein in tail groups", which the examiner respectfully submits, does not make sense. Claim 1 recites the limitation "a ligand" in line 5. There

is uncertain antecedent basis for this limitation in the claim, because it is unclear if "a ligand" in line 5 is the same or different from "a ligand" in line 1. The term "more strongly" in claim 1 is a relative term which renders the claim indefinite. The term "more strongly" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree of interacting, and one of skill in the art would not be reasonably apprised of the metes and bounds of the claimed invention.

Claims 2 and 6 recite the term "analogue", as in "peptide analogue" and "lipidic amino acid analogue", respectively, which renders the claims vague and indefinite, because analogue may be functional and embrace many different structures, and therefor the term is capable of different meanings. Therefore the practitioner would not be reasonably apprised of the metes and bounds of the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

11. Claims 1-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Crabtree et al., WO 95/02684 A1.

The claims are drawn to a composition for interacting with a ligand, which composition comprises a non-covalent association of a plurality of distinct conjugates, each conjugate comprising a head group and a tail group, wherein tail groups of the conjugates form a hydrophobic aggregation and the conjugates are movable within the association so that, in the presence of a ligand, at least two of the head groups are appropriately positioned to form an epitope capable of interacting with the ligand more strongly than each of head groups individually; and variations thereof.

Crabtree et al., WO 95/02684 A1, throughout the publication, disclose chimeric proteins which contain at least one ligand-binding (or "receptor") domain fused to an action domain within a cell (pp. 3-4), wherein the receptor domain comprises amino acids and peptide, wherein the chimeric protein may homodimerize or heterodimerize (pp. 14-15) to the ligand; a composition for interacting with a ligand, which composition comprises a non-covalent association of a plurality of distinct conjugates, each conjugate comprising a head group of various receptor domains, (which would inherently include at least acidic and basic amino acids) and an optional and sometimes preferred membrane binding domain which includes a transmembrane domain or an attached lipid for translocating the fused protein to the cell surface/membrane and retaining the protein bound to the cell surface membrane (pp. 20, 29-30, Figure 15) reading on a tail group, wherein tail groups of the conjugates form a hydrophobic aggregation and the conjugates are movable by virtue of the transmembrane domain,

within the association so that, in the presence of a ligand, at least two of the head groups are appropriately positioned to form an epitope capable of interacting with the ligand more strongly than each of head groups individually, because the bind as more sites. Crabtree at p. 30 discloses a lipid retention domain having from about 12 to 24 carbon atoms, particularly 14 carbon atoms, and more particularly myristoyl, joined to glycine (reading on a spacer), as in claims 6-10. Crabtree et al., e.g., at p. pp. 10-11, disclose that the chimeric proteins may be expressed in a cell, reading on a lamellar structure, micelle or liposome, as in claim 11. Crabtree et al., at pp. 10-11, teach the claimed composition of the intended use, and also disclose and contemplate the use of the chimeric proteins as pharmaceuticals.

12. Claims 1-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Capon et al., WO 96/23881 A1.

Capon et al., WO 96/23881 A1, throughout the publication and abstract, disclose compositions for interacting with an inducer, reading on the claimed ligand, and at, e.g., pp. 1-3 and Figure 1, disclose compositions that are chimeric receptor proteins, which comprises a non-covalent association of a plurality of distinct conjugates, each conjugate comprising an extracellular inducer binding domain (e.g., pp. 6-7, 11) (such as IL-2, IL-3, IL-6 receptors, p. 18, or antibody binding regions, p. 23, which would inherently include at least acidic and basic amino acids, as in claim 5) and that become associated with each other by dimerization or oligomerization and cluster, reading on the claimed head group; a transmembrane domain (e.g., p. 7, 22), teaching that the

transmembrane domain may be an artificial hydrophobic amino acid sequence which spans the plasma domain, which further reads on a hydrophilic spacer groups as in claims 8 and 9 of the instant application); and a cytoplasmic effector function signaling domain; said transmembrane and cytoplasmic effector function signaling reading on the claimed tail group, wherein transmembrane domains of the tail groups of the conjugates would inherently form a hydrophobic aggregation with the conjugates movable within the association so that, in the presence of a ligand, at least two of the head groups would be appropriately positioned to form an epitope capable of interacting with the ligand more strongly than each of head groups individually. Capon et al., at p. 10, teach linkers that link together any of the aforementioned domains (further reading on the claimed spacer). Capon et al., at p. 13, teach a transmembrane domain that is a myristylation-targeting domain that may be linked to the N-terminus of a domain to allow for membrane association, as in claims 6 and 7 of the instant application). Capon et al., disclose that the chimeric polypeptides may be expressed in a cell, reading on a lamellar structure, micelle or liposome, as in claim 11. Capon et al. teach the claimed composition, regardless of the intended use, and also disclose and contemplate the use of chimeric polypeptides as mendicants, etc. (see abstract, p. 14, top).

13. Claims 1-6 and 8-12 are rejected under 35 U.S.C. 102(e) as being anticipated by Ueda et al., US 2003/0095962 A1.

Ueda et al., US 2003/0095962 A1, throughout the publication, e.g. the Examples, disclose chimeric polypeptides having the property that they associate with each other

when a particular antigen is present, (e.g., para 0029, 0043, 0046-0049, 0063), which read on the claimed composition comprising a non-covalent association of a plurality of distinct conjugates; and wherein the polypeptide have variable domain sequence that are polypeptides or proteins or fragments thereof, including antibody variable sequences, (which would inherently include at least acidic and basic amino acids, as in claim 5), and where the variable domain sequence read on the claimed head group; and effector sequences and transmembrane sequences (para 0040-0041), which read on the claimed tail groups, wherein the tail groups of the conjugates form a hydrophobic aggregation and the conjugates are movable within the association (para 00620), so that, in the presence of an "antigen", (para 0043)reading on the claimed ligand ligand, at least two of the head groups would be appropriately positioned to form an epitope (i.e., capable of binding a ligand, as in the instant specification and claims) and capable of interacting with the ligand more strongly than each of head groups individually (see e.g., para 0049). Ueda et al. at para 0064, teach amino acid peptides (e.g., EpoR subunits) that connect variable, "head" regions and with effector "tail" regions, and which read on spacers, as in claim 8. Ueda et al., in the Examples, disclose that the chimeric polypeptides may be expressed in a cell, reading on a lamellar structure, micelle or liposome, as in claim 11. Ueda et al. teach the claimed composition, regardless of the intended use, and also disclose and contemplate the use of chimeric polypeptides as mendicants, etc.

14. Claims 1-12 are rejected under 35 U.S.C. 102(b, e) as being anticipated by Toth et al., 5,882,645 (IDS entered 12/27/2001, cite no. 2).

Toth et al., 5,882,645, throughout the patent, disclose Lipid-Core Peptide compounds (e.g., col. 5, especially line 13) that are compositions for interacting eliciting an immune response and capable of binding with specific antibodies, taken to read on the claimed ligands (see, e.g., col. 1-2); and where the composition comprises a non-covalent association of a plurality of distinct compounds, reading on the claimed conjugates, (at col. 3), each conjugate comprising at least 2 amino acids that can be bound to pharmaceutically active substitutents, reading on the claimed head group, and a lipophilic anchor, reading on the claimed tail group, wherein tail groups of the conjugates form a hydrophobic aggregation and the conjugates are movable within the association so that, in the presence of a ligand, at least two of the head groups are appropriately positioned to form an epitope capable of interacting with the ligand more strongly than each of head groups individually. Toth et al. at col. 11 teach the production of rabbit antibodies specific for the amino acids of the head groups, which would bind more than one of the against the peptide compounds. Toth et al., at col. 4., line 34, col. 6-7, bridging paragraph, teach a linker which reads on the spacer of the claimed invention. Toth teaches molecules for pharmaceutical purposes (col. 5). Toth et al. col. 11, teach lipid cores that are 13 carbon atoms long. Toth teach lipid anchors will incorporate into liposomes or cell membrane, (at col. 2, especially line 24, col. 5, esp. line 61).

Conclusion

15. Claims 1-12 are rejected.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark L. Shibuya whose telephone number is (571) 272-0806. The examiner can normally be reached on M-F, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Mark L. Shibuya
Examiner
Art Unit 1639

ms

Continuation of Attachment(s) 6). Other: Notice to Comply & Error Report.

Notice to Comply	Application No. 10/019,052	Applicant(s) NEW
	Examiner SHIBUYA	Art Unit 1639

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant must file the items indicated below within the time period set in the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

☒ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).

☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).

☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).

☒ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."

☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).

☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).

☐ 7. Other: Please see attached sheet.

Applicant Must Provide:

☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".

☐ An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.

☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (571) 272-2510
For CRF Submission Help, call (571) 272-2501/2583.
PatentIn Software Program Support
Technical Assistance.....703-287-0200
To Purchase PatentIn Software.....703-306-2600

PLEASE RETURN A COPY OF THIS NOTICE WITH YOUR REPLY

STIC Biotechnology Systems Branch

RAW SEQUENCE LISTING ERROR REPORT

The Biotechnology Systems Branch of the Scientific and Technical Information Center (STIC) detected errors when processing the following computer readable form:

Application Serial Number: 10/019,052
Source: IFW16
Date Processed by STIC: 2/25/05

THE ATTACHED PRINTOUT EXPLAINS DETECTED ERRORS.
PLEASE FORWARD THIS INFORMATION TO THE APPLICANT BY EITHER:
1) **INCLUDING A COPY OF THIS PRINTOUT IN YOUR NEXT COMMUNICATION TO THE APPLICANT, WITH A NOTICE TO COMPLY or,**
2) **TELEPHONING APPLICANT AND FAXING A COPY OF THIS PRINTOUT, WITH A NOTICE TO COMPLY**

FOR CRF SUBMISSION AND PATENTIN SOFTWARE QUESTIONS, PLEASE CONTACT MARK SPENCER, TELEPHONE: 571-272-2510; FAX: 571-273-0221

TO REDUCE ERRORED SEQUENCE LISTINGS, PLEASE USE THE CHECKER VERSION 4.2.2 PROGRAM, ACCESSIBLE THROUGH THE U.S. PATENT AND TRADEMARK OFFICE WEBSITE. SEE BELOW FOR ADDRESS:

http://www.uspto.gov/web/offices/pac/checker/chkrnote.htm

Applicants submitting genetic sequence information electronically on diskette or CD-Rom should be aware that there is a possibility that the disk/CD-Rom may have been affected by treatment given to all incoming mail. Please consider using alternate methods of submission for the disk/CD-Rom or replacement disk/CD-Rom. Any reply including a sequence listing in electronic form should NOT be sent to the 20231 zip code address for the United States Patent and Trademark Office, and instead should be sent via the following to the indicated addresses:

1. EFS-Bio (<http://www.uspto.gov/ebc/efs/downloads/documents.htm> , **EFS Submission User Manual** - ePAVE)
2. **U.S. Postal Service:** Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450
3. **Hand Carry, Federal Express, United Parcel Service, or other delivery service (EFFECTIVE 01/14/05):** U.S. Patent and Trademark Office, Mail Stop Sequence, Customer Window, Randolph Building, 401 Dulany Street, Alexandria, VA 22314

Revised 01/24/05

Raw Sequence Listing Error Summary

ERROR DETECTED **SUGGESTED CORRECTION** **SERIAL NUMBER:** 10/019,052

ATTN: NEW RULES CASES: PLEASE DISREGARD ENGLISH "ALPHA" HEADERS, WHICH WERE INSERTED BY PTO SOFTWARE

1	Wrapped Nucleics Wrapped Aminos	The number/text at the end of each line "wrapped" down to the next line. This may occur if your file was retrieved in a word processor after creating it. Please adjust your right margin to .3; this will prevent "wrapping."
2	Invalid Line Length	The rules require that a line not exceed 72 characters in length. This includes white spaces.
3	Misaligned Amino Numbering	The numbering under each 5th amino acid is misaligned. Do not use tab codes between numbers; use space characters, instead.
4	Non-ASCII	The submitted file was not saved in ASCII(DOS) text, as required by the Sequence Rules. Please ensure your subsequent submission is saved in ASCII text.
5	Variable Length	Sequence(s)____contain n's or Xaa's representing more than one residue. Per Sequence Rules, each n or Xaa can only represent a single residue. Please present the maximum number of each residue having variable length and indicate in the <220>-<223> section that some may be missing.
6	PatentIn 2.0 "bug"	A "bug" in PatentIn version 2.0 has caused the <220>-<223> section to be missing from amino acid sequences(s) _____. Normally, PatentIn would automatically generate this section from the previously coded nucleic acid sequence. Please manually copy the relevant <220>-<223> section to the subsequent amino acid sequence. This applies to the mandatory <220>-<223> sections for Artificial or Unknown sequences.
7	Skipped Sequences (OLD RULES)	Sequence(s) _____ missing. If intentional, please insert the following lines for each skipped sequence: (2) INFORMATION FOR SEQ ID NO:X: (insert SEQ ID NO where "X" is shown) (i) SEQUENCE CHARACTERISTICS: (Do not insert any subheadings under this heading) (xi) SEQUENCE DESCRIPTION:SEQ ID NO:X: (insert SEQ ID NO where "X" is shown) This sequence is intentionally skipped Please also adjust the "(ii) NUMBER OF SEQUENCES:" response to include the skipped sequences.
8	Skipped Sequences (NEW RULES)	Sequence(s) _____ missing. If intentional, please insert the following lines for each skipped sequence. <210> sequence id number <400> sequence id number 000
9	Use of n's or Xaa's (NEW RULES)	Use of n's and/or Xaa's have been detected in the Sequence Listing. Per 1.823 of Sequence Rules, use of <220>-<223> is MANDATORY if n's or Xaa's are present. In <220> to <223> section, please explain location of n or Xaa, and which residue n or Xaa represents.
10	Invalid <213> Response	Per 1.823 of Sequence Rules, the only valid <213> responses are: Unknown, Artificial Sequence, or scientific name (Genus/species). <220>-<223> section is required when <213> response is Unknown or is Artificial Sequence
11	Use of <220>	Sequence(s) _____ missing the <220> "Feature" and associated numeric identifiers and responses. Use of <220> to <223> is MANDATORY if <213> "Organism" response is "Artificial Sequence" or "Unknown." Please explain source of genetic material in <220> to <223> section. (See "Federal Register," 06/01/1998, Vol. 63, No. 104, pp. 29631-32) (Sec. 1.823 of Sequence Rules)
12	PatentIn 2.0 "bug"	Please do not use "Copy to Disk" function of PatentIn version 2.0. This causes a corrupted file, resulting in missing mandatory numeric identifiers and responses (as indicated on raw sequence listing). Instead, please use "File Manager" or any other manual means to copy file to floppy disk.
13	Misuse of n/Xaa	"n" can only represent a single nucleotide; "Xaa" can only represent a single amino acid

IFW16

RAW SEQUENCE LISTING DATE: 02/25/2005
PATENT APPLICATION: US/10/019,052 TIME: 10:07:47

Input Set : A:\1417-212.txt.txt
Output Set: N:\CRF4\02252005\J019052.raw

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  3 <110> APPLICANT: New, Roger
  4       Toth, Isrvan
  6 <120> TITLE OF INVENTION: EPITOPES FORMED BY NON-COVALENT ASSOCIATION OF CONJUGATES
  8 <130> FILE REFERENCE: 1417-212
 10 <140> CURRENT APPLICATION NUMBER: 10/019,052
 11 <141> CURRENT FILING DATE: 2002-04-22
 13 <160> NUMBER OF SEQ ID NOS: 7
 15 <170> SOFTWARE: PatentIn version 3.2
 17 <210> SEQ ID NO: 1
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 19 <212> TYPE: PRT
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 28 1
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 64 <220> FEATURE:
 65 <223> OTHER INFORMATION: Head group
 67 <400> SEQUENCE: 4
 69 Glu Gln Ser His
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pp 1-2

Does Not Comply
Corrected Diskette Needed

what is its source?
give source of genetic material
(see item 11 on Error Summary Sheet)

RAW SEQUENCE LISTING DATE: 02/25/2005
PATENT APPLICATION: US/10/019,052 TIME: 10:07:47

Input Set : A:\1417-212.txt.txt
Output Set: N:\CRF4\02252005\J019052.raw

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83 Tyr Gln Ser His
84 1
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95 <400> SEQUENCE: 6
97 Glu Tyr Gln Ser His
98 1 5
101 <210> SEQ ID NO: 7
102 <211> LENGTH: 4
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104 <213> ORGANISM: Artificial Sequence
106 <220> FEATURE:
107 <223> OTHER INFORMATION: Head group
109 <400> SEQUENCE: 7
111 Leu Ser Glu Gln
112 1

VERIFICATION SUMMARY DATE: 02/25/2005
PATENT APPLICATION: US/10/019,052 TIME: 10:07:48

Input Set : A:\1417-212.txt.txt
Output Set: N:\CRF4\02252005\J019052.raw